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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,583	04/06/2006	Charles A. Blum	60884(72021)	2022
21874	7590	08/28/2008	EXAMINER	
EDWARDS ANGELI, PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205			BALASUBRAMANIAN, VENKATARAMAN	
ART UNIT	PAPER NUMBER	1624		
MAIL DATE	DELIVERY MODE	08/28/2008 PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/564,583	BLUM ET AL.
	Examiner /Venkataraman Balasubramanian/	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on 13 January 2006.
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4)  Claim(s) See Continuation Sheet is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) \_\_\_\_\_ is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) 1, 2, 4, 5, 7-10, 12-14, 17-19, 22, 23, 25, 29, 32-38, 41, 60, 61, 75-78, 82-84, 87, 88 and 92 are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some \* c)  None of:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5)  Notice of Informal Patent Application
- 6)  Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,5,7-10,12-14,17-19,22,23,25,29,32-38,41,60,61,75-78,82-84,87,88 and 92.

#### **DETAILED ACTION**

The preliminary amendment filed on 1/13/2006 is made of record. Claims 1, 2, 4, 5, 7-10, 12-14, 17-19, 22, 23, 25, 29, 32-38, 41, 49, 60, 61, 75-78, 82-84, 87, 88 and 92 are now pending.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 2, 4, 5, 7-10, 12, 13, 49, 60, 61, 75-78, 82-84, 87, 88 and 92 drawn to compound of formula shown in claim 1 wherein X is N, namely 1, 3, 5,-triazine compound, composition and method of use.

Group II, claims 1, 2, 4, 5, 7-10, 12-14, 17-19, 22, 23, 25, 29, 32-38, 41, 49, 60, 61, 75-78, 82-84, 87, 88 and 92 drawn to compound of formula shown in claim 1, 17, 41, 49 wherein X is CR<sub>x</sub> or Y is N, namely pyrimidine compound, composition and method of use.

Group III, claims 17-19, 22, 23, 25 and 41, drawn to compound of formula shown in claim 17 and 41, wherein Y is CR<sub>y</sub>, namely pyridine compound.

The inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Where there is lack of unity the requirement for restriction is proper- See MPEP 803.02. The requirement for unity of invention is two-fold: (1) common utility and (2) sharing a substantial structural feature disclosed as being essential to the utility. Both these conditions are to be met with.

Instant claims do not meet both these conditions.

Invention I, II and III are independent and distinct from each other because they are directed to structurally dissimilar compounds that lack common core, namely, various heterocyclic groups such as pyridyl, pyrimidinyl, and triazinyl cores for Y or X choices. Consequently, the groups require separate prior art searches. They can be made and used independently. Art which may render obvious or anticipate one of the groups would not necessarily do the same for the other group. For example prior art cited in the International Search Report and the Information Disclosure Statement may not be applicable to all the above groups. Each can support a patent as the compounds of each group are capable of being utilized alone not in combination with other members listed in the Markush group.

Except for the NH group, every ring and substituents in the core of compound of formula I is varied and it cannot be said that the NH attached to any variable ring group essentially contribute to the utility recited in the claims. Thus, the common structural feature essential for the said utility is not met with. In addition, common utility requirement is also not met with as evident from the claims that these compounds can be used for pain, asthma, chronic obstructive pulmonary disease, cough, hiccup, obesity, urinary incontinence, overactive bladder, exposure to capsaicin, burn or

irritation due to exposure to heat, burn or irritation due to exposure to light, burn, bronchoconstriction or irritation due to exposure to tear gas, air pollutants or pepper spray, or burn or irritation due to exposure to acid. In addition, prior art cited in the Information Disclosure Statement and International search report clearly state other uses for the instant compounds.

Thus, both the criteria set forth for unity of invention is not met with.

In view of distinct nature of each invention, the restriction requirement is set forth in writing.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different structural make-up;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### **Conclusion**

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is (571) 272-0661.

The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>.  
Should you have questions on access to the Private PAIR system, contact the  
Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

/Venkataraman Balasubramanian/

Primary Examiner, Art Unit 1624